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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/529,937 06/30/00 MEIRINHOS DA CRUZ

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EXAMINER

KISHORE.G

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

09/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.

09/529,937

Applicant(s)

Da Cruz

Examiner

Gollamudi Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved, b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-592) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-949) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

The preliminary amendment dated 4-30-00 is acknowledged.

Claims included are 1-22.

Claim Rejections - 35 U.S.C. § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Dinitroaniline is a specific compound; hence it is unclear as to what applicant intends to convey by 'one dinitroaniline' in the independent claims. What is the difference between 'incorporated' and 'encapsulated' in claim 1?

What is being conveyed by 'characterized by the fact of mixing populations of particles, respectively bigger and lower than 100 nm' in claim 5?

The examiner suggests restructuring claims 6 and 19. The molar ratios, hydrogenation or no hydrogenation appear to be not important and thus, it is unclear why they are recited. Some of the lipids recited do not form liposomes by themselves. The examiner suggests a Markush format deleting 'other synthetic lipids' and 'derivatives'.

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'Small' in claim 10 is a relative term and hence renders the claim indefinite.

'What is a non-saline solution' as recited in claim 11?

'any other sugar solution' in claim 12 is not a positive recitation.

The independent claim 7 doesn't recite any process step of obtaining specific sizes of liposomes; yet the dependent claim 13 recites 'mixing different diameter particle populations'. This step is not meaningful if the process in claim 7 leads to liposomes of different sizes.

What is being conveyed in claim 14? It is confusing.

In claim 15, applicant deletes 'according to claim 14'; what is being conveyed through this claim? Similar is the case with claims 16-18. The claims do not contain any specific limitations and do not further limit the parent claims.

What is being conveyed by 'process according to claim 1 when prepared by a process according to any of the claims 7-20' in claim 21?

3. Claim 22 provides for the use of the composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 22 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101.

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See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by wo 95/31970 of record.

WO discloses liposomal formulations containing trifluralin; the liposomes are made of phosphatidylcholine. Since the process of preparation in the prior art results in a liposome population of different sizes, the reference meets the requirements of dependent claims (note the abstract and claims).

Claim Rejections - 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention

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was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicant's statements of prior art in view of Steck (4,186,183), Rao (4,594,241) individually or in combination or vice versa.**

Applicant in the paragraph bridging pages 3 and 4 of the specification indicate that the herbicide, trifluralin is a well-known anti-leishmania drug.

Steck teaches liposomal carriers for the treatment of leishmaniasis (note the abstract). According to Steck the liposomes are taken up rapidly by cells and intra-cellular lysosomes of the reticuloendothelial system and that the characteristics of liposomes suggested that they might have a potential for application of carriers for anti-leishmania agents. Steck also teaches that the cells and tissues in which the liposomes are readily taken up are the very locations in which the Leishmania organisms predominantly reside (note col. 2, lines 6-26). The anti-leishmania drug taught by Steck however, is not the claimed drug.

Rao similarly teaches the effectiveness of the liposomally encapsulated anti-leishmania drugs against this organism (note the abstract, examples and claims). The anti-leishmania drug taught by Rao however, is not the claimed compound.

The use of the liposomes as carriers of trifluralin would have been obvious to one of ordinary skill in the art because of effectiveness of liposomes as carriers of anti-leishmania drugs taught by Steck and Rao. Alternately, the use of trifluralin in the liposomes of Steck

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or Rao would have been obvious to one of ordinary skill in the art with the expectation of obtaining the benefits of the liposomes since trifluralin is a art known anti-leishmania drug.

a. Claims 7-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicant's statements of prior art in view of Steck (4,186,183), Rao (4,594,241) individually or in combination or vice versa as set forth above, further in view of GB 2 002 319: or wo 95/31970 cited above, further in view of GB 2 002 319.

Neither Steck nor Rao nor WO teach the dehydration of the liposomes and hydrating again.

GB teaches that liposomes can be dehydrated for storage as a stable powder. According to GB such dehydrated powders can be stored for long periods and from which a dispersion of liposomes can be reconstituted (note the abstract).

Dehydrating the liposomes of Steck or Rao or WO would have been obvious to one of ordinary skill in the art because GB teaches that the liposomal powders can be stored for a long time.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600